

## REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 3, 10-15, 18, 21-25, and 31 are currently being amended. Support for the claim amendments can be found, at least, in the specification as filed, e.g., paragraphs 0088, 0137, , the claims as filed, e.g., claim 18, and the figures, e.g., figure 7a. No new matter has been added.

This amendment changes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-26 and 31 are now pending in this application.

## Drawings

The drawings were objected to because Figures 2A and 2B were referred to in the written description, but not included in the drawings. The specification has been amended to correct the references to Figure 2A and Figure 2B. As such, the objections to the drawings have been corrected based on the amendments to the specification.

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include certain reference signs, 231, 233, 235, 238, 242, and 245, as mentioned in the description. The specification has been amended to correct the references to the certain reference signs. As such, the objections to the drawings have been corrected based on the amendments to the specification.

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because the specification does not include certain reference signs, 1004, 1902, 1903, and 2302, as illustrated in the drawings. The specification has been amended to include the certain reference signs that were illustrated in the drawings. As such, the objections to the drawings have been corrected based on the amendments to the specification.

### **Objections**

Claims 10, 13, 14, 15, and 31 were objected to because of informalities in the claim language. Claim 10 has been amended to correct the antecedent basis to “the thermal medium.” Claims 13 and 14 have been amended to correct the antecedent basis to “the controller.” Claim 15 has been amended to correct the antecedent basis to “the power source.” Claim 31 has been amended to correct the antecedent basis to the “the first tube” and “the second tube.” As such, the objections to claims 10, 13, 14, 15, and 31 have been corrected based on the amendments to the claims included herein.

### **Rejections**

#### 35 U.S.C. 112, Second Paragraph

Claims 1-26 and 31 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 11, 12, 22, 23, 24, and 25 were amended to correct the antecedent basis to “the fluid delivery tube.” Claims 3, 18, and 21 were amended to correct the antecedent basis to “the second tube.” As such, claims 1-26 and 31, as amended, are now in a condition for allowance since the antecedent basis has been corrected.

35 U.S.C. 102 and 103

Claims 1-8, 11-14, 16-19, 22-25, and 31 were rejected under 35 U.S.C. 102(e) as being anticipated by Lenker (U.S. 6,746,439). Claims 9, 10, and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker. Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker in view of Swenson (U.S. 5,195,976). Claims 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker in view of Cassidy et al. (U.S. 6,175,688).

The independent claims, 1 and 31, as now amended, include “two or more thermal sensors” and “the heating element being controlled based on temperature data from the two or more thermal sensors to generate a determined heat gradient through the fluid within the tube.” The cited references, Lenker, Swenson, and Cassidy, do not describe a system for heating a fluid for delivery into a body of a patient that includes “two or more thermal sensors” and “the heating element being controlled based on temperature data from the two or more thermal sensors to generate a determined heat gradient through the fluid within the tube.”

Regarding the first reference, Lenker describes an apparatus for controlling the temperature of fluids being administered to patients and includes a temperature sensor. (Lenker: Abstract; Figure 1). The apparatus controls the temperature of the fluids by locating the temperature measurement probe at the end of the I.V. tubing nearest the patient and then “overheating the fluid so that it reaches the patient at the desired temperature.” (emphasis added) (Lenker: col. 2, lines 5-12; col. 3, line 66 to col. 4, line 2; see also Figure 1). Lenker does not describe utilizing two or more thermal sensors, but describes utilizing a single temperature located near the patient as illustrated by the temperature probe 128 in Figure 1 of Lenker.

Furthermore, Lenker does not describe controlling the heating element based on temperature data from the two or more thermal sensors to generate a determined heat gradient

through the fluid within the tube. Rather, Lenker describes overheating the fluid based on a single temperature sensor close to the patient. On the other hand, as described in the specification of the present application, the present application minimizes the variation in temperature of fluid between the source of the fluid and the patient. (Present Application: paragraph 0055). In contrast, the apparatus as described in Lenker “provides for overheating of the fluid so that it cools down to the desired temperature (usually body temperature) by the time it reaches the patient.” (emphasis added) (Lenker: Abstract). In contrast, the present application generates a determined heat gradient through the fluid within the tube based on the temperature data and therefore prevents such dramatic overheating as described by Lenker.

Regarding the second reference, Swenson describes an apparatus with an intravenous infusion assembly, a heat exchanger assembly, a controller subassembly, and an energy source subassembly. (Swenson: col. 5, line 66 to col. 6, line 4). The heat exchanger assembly includes heat exchangers, a flow sensor, and an initial and final temperature sensors. (Swenson: col. 6, lines 24-35). After the controller receives a flow signal from the flow sensor, the controller meters electrical power to the heat exchangers based on the temperatures and the IV fluid flow. (Swenson: col. 12, line 66 to col. 13, line 11; col. 13, lines 39-51). As such, Swenson utilizes fluid flow information to determine when to turn the heat exchangers on or off. In contrast, the present application controls the heating element based on temperature data from the two or more thermal sensors to generate a determined heat gradient through the fluid within the tube. In other words, the present application is not turned off or on based on fluid flow, but minimizes the variation in temperature of fluid between the source of the fluid and the patient utilizing the determined heat gradient. (Present Application: paragraph 0055).

Regarding the third reference, Cassidy describes a patient wearable intravenous fluid heater with a heat exchanger for heating the fluid via a heating element and temperature sensors for sensing the entering and existing temperatures of the fluid. (Cassidy: Abstract; see also Figure 7). Cassidy further describes a controller for controlling the heating element based upon the temperature of the fluid exiting the heat exchanger. (Cassidy: Abstract; col. 8, lines 29-42;

col. 10, lines 18-37; see also Figure 7). In contrast, the present application controls the heating element based on temperature data from the two or more thermal sensors to generate a determined heat gradient through the fluid within the tube. Rather, Cassidy describes using the input temperature information for the warning system, controlling the heat exchanger based on the output temperature, and determining a fluid rate based on the input temperature. (Cassidy: col. 8, lines 48-52; col. 10, lines 12-17; col. 14, lines 13-20). Furthermore, Cassidy describes controlling the heat exchanger by determining whether the output temperature is above or below a target temperature and turning the heat exchanger off or on accordingly. (Cassidy: col. 10, lines 18-65; see also Figures 10-11). Thus, Cassidy describes using input temperature to control flow rate and output temperature to independently control the heat exchanger. Nowhere does Cassidy describe or suggest using the input temperature and the output temperature in combination to control the heat exchanger. On the other hand, the present application controls the heating element based on temperature data from the two or more thermal sensors to generate a determined heat gradient through the fluid within the tube.

Accordingly, Lenker, Swenson, and Cassidy do not describe a system that includes the elements of independent claims 1 and 31. As such, independent claims 1 and 31 and claims 2-26, which depend from claim 1, are now in a condition for allowance based on their distinctions from the cited references.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or

incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Oct. 14, 2008 By 

FOLEY & LARDNER LLP  
Customer Number: 48329  
Telephone: (617) 342-4093  
Facsimile: (617) 342-4001

Ralph Trementozzi  
Registration No. 55,686

Christopher E. Everett  
Registration No. 51,659

Attorneys for Applicant